DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 30 2005

4236 5 AUG 31 P1:31

Geoffrey Allan, Ph.D.
President & Chief Executive Officer
Insmed, Incorporated
P.O. Box 2400
Glen Allen, VA 23058-2400

Re: Docket No. 2005P-0322/CP1

Dear Dr. Allan:

This letter is in response to your citizen petition submitted by Insmed, Inc. (Insmed) on August 11, 2005. You ask that the Food and Drug Administration (FDA) immediately deny approval of new drug application (NDA) 21-839, submitted by Tercica, Inc. (Tercica) for Increlex (mecasermin [rDNA origin] injection) for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. In your petition, you note that this NDA was granted priority review and assigned an action goal date of August 31, 2005. For the reasons summarized below and addressed elsewhere in agency records, your petition is denied.

FDA carefully reviewed the issues raised in the citizen petition, in Tercica's August 22, 2005, comment to the petition, and in Insmed's August 25, 2005, letter in response to Tercica's comment, including the attached letter from Louis E. Underwood, M.D., dated July 28, 2005. [1]

The issues raised in your petition are discussed and considered in some detail in the FDA office director's decisional memorandum for NDA 21-839, particularly to the extent that the issues relate to the approvability of Tercica's NDA.[2] As described in that memorandum, FDA has determined that the arguments against approval raised in your petition were not persuasive, and that Tercica adequately demonstrated that Increlex is safe and effective under the conditions of use described in its labeling. Based on this memorandum, which I have reviewed, I am denying your petition.

Sincerely,

Steven Galson, M.D., M.P.H.
Acting Director
Center for Drug Evaluation and Research

[1] We note that although your petition was filed on August 10, 2005, less than one month before the date on which you expected the agency to act on the Tercica NDA, the majority of data on which Insmed relies in support of its scientific challenge was available to Insmed several months and, in most cases, more than a year before the petition was submitted.

[2] The office director's memorandum will be released as part of the publicly available record of NDA 21-839, following routine redaction of any non-public information.

2005P-0322

PDN 1